

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
200.1079US

SERIAL NO.: 09/154,354

10/057,632

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE:  
September 17, 1998

GROUP: 1627 1639

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLAS S	TRANSLATION	
													YES	NO
	AA	0	6	5	4	2	6	3	05/24/95	EP (A1)	A61K	31/135		
	AB	0	6	5	4	2	6	3	05/24/95	EP (B1)	A61K	31/135		
	AC	9	7	1	7	9	7	8	05/22/97	WO	A61K	33/00		
	AD	9	7	2	5	9	8	8	07/24/97	WO	A61K	31/495		
	AE	9	7	3	2	8	5	7	09/12/97	WO	C07D	241/104		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AF	Dray et al. New Pharmacological Strategies for Pain Relief. <u>Annual Review of Pharmacology &amp; Toxicology</u> , 36, pp. 253-280. (1996).
AG	Brasseur, L. Revue des therapeutiques pharmacologiques actuelles de la douleur. <u>Drugs</u> , 53 Suppl 2, pp. 10-17. (1997)
AH	Rang et al. New molecules in analgesia. <u>British Journal of Anesthesia</u> , 75, pp. 145-156 (1995)
AI	Beaver, WT. Combination Analgesics. <u>American Journal of Medicine</u> , 77 (Suppl 3A), pp. 38-53. (1984).
AJ	Beaver, WT. Chapter 29: Nonsteroidal Antiinflammatory Analgesics and Their Combinations with Opioids. In <u>Evaluation and Treatment of Chronic Pain</u> , 2 <sup>nd</sup> ed., William & Wilkins pp. 363-383. (1992).
AK	Goodman & Gilman's. <u>The Pharmacological Basis of Therapeutics</u> , 9 <sup>th</sup> Edition. McGraw-Hill, New York, pp 535 and 551-552.
AL	Picard et al. Ketorolac potentiates morphine in postoperative patient-controlled analgesia. <u>Pain</u> , 73, 3 pp. 401-406. (1997).
AM	Elches et al. Continuous Intravenous Administration of Ketorolac Reduces Pain and Morphine Consumption After Total Hip or Knee Arthroplasty. <u>Anesthesia &amp; Analgesia</u> , 81 (6), pp. 1175-1180. (1995).
AN	Hodsmen et al. The morphine sparing effects of diclofenac sodium following abdominal surgery. <u>Anaesthesia</u> , 42(9), pp. 1005-1008. (1987).
AO	Kaasalainen et al. Developments in the treatment of cancer pain in Finland: The third nation-wide survey. <u>Pain</u> , 70, 2-3, pp. 175-183. (1997).
AP	Sunshine et al. Analgesic Efficacy of a Hydrocodone with Ibuprofen Combination Compared with Ibuprofen Alone for the Treatment of Acute Postoperative Pain. <u>Journal of Clinical Pharmacology</u> , 37 (10), pp. 908-915. (1997).
AQ	Insel. Chapter 27: Analgesic-Antipyretic and Anti-inflammatory Agents. In Hardman, ed., <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , 9 <sup>th</sup> Edition. McGraw-Hill, New York, pp. 654-655. (1996).
AR	Polisson. Non-steroidal Anti-inflammatory Drugs: Practical and Theoretical Consideration in Their Selection. <u>The American Journal of Medicine</u> , 100 (Suppl 2A), pp. 2A-31S - 2A-36S. (1996).
AS	Vane, J. Towards a better aspirin. <u>Nature</u> , 367, pp. 215-216. (1994).
AT	Simon, L.S. Nonsteroidal Antiinflammatory Drugs and Their Effects: The Importance of COX 'Selectivity'. <u>Journal of Clinical Rheumatology</u> , 2 (3), pp. 135-140. (1996)

EXAMINER

DATE CONSIDERED

6/29/04

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10/05/97 632

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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

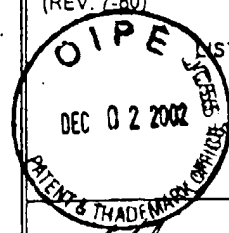
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| BA | Van Ryn et al. Selective cyclooxygenase-2 inhibitors: pharmacology, clinical effects, and therapeutic potential. <u>Expert Opinion On Investigational Drugs</u> . pp. 609-614. (1997).   |
| BB | Vane et al. New insights into the mode of action of anti-inflammatory drugs. <u>Inflammation Research</u> . 44, (No.1), pp 1-10 (1995).  |
| BC | Engelhardt. Meloxicam: A Preferential Inhibitor of COX-2. <u>British Journal of Rheumatology</u> . 34, Abstract Suppl. 1, p. 48. (1995). Abstract.   |
| BD | Lane, N.E. Pain Management in Osteoarthritis: The Role of COX-2 Inhibitors. <u>Journal of Rheumatology</u> . Vol. 24, Suppl 49, pp. 20-24. (1997).   |
| BE | Boyce et al. L-745,337: A Selective Inhibitor of Cyclooxygenase-2 Elicits Antinociception But Not Gastric Ulceration In Rats. <u>Neuropharmacology</u> Vol. 33, pp. 1609-1611. (1994).   |
| BF | Donnelly et al. COX-II Inhibitors - a new generation of safer NSAIDS? <u>Alimentary Pharmacology and Therapeutics</u> , 11, 2, pp. 227-236. (1997).  |
| BG | Wallace, J.L. Nonsteroidal Anti-inflammatory Drugs and Gastroenteropathy: The Second Hundred Years. <u>Gastroenterology</u> . 112, 3, pp. 1000-1016. (1997).   |
| BH | Robinson, D.R. Regulation of Prostaglandin Synthesis by Antiinflammatory Drugs. <u>J Rheumatology</u> , 24, Suppl. 47, pp. 32-39. (1997).  |
| BI | Tannenbaum et al. An Evidence-Based Approach to Prescribing NSAIDS in Musculoskeletal Disease: A Canadian Consensus. <u>Canadian Medical Association Journal</u> , 155, 1, pp 77-88. (1996).   |
| BJ | Mehlisch et al. Analgesic Efficacy and Plasma Levels of a Highly Selective Inhibitor of COX-2 (SC-58635, SC) in Patients with Postsurgical Dental Pain. <u>Journal of Clinical Pharmacology</u> , 37, 9, 863. (1997). Abstract.  |
| BK | Dammann. Selective COX-2 Inhibition: Its Relevance for NSAID-Gastrointestinal Toxicity. <u>Gut</u> , 39, Suppl. 3, A151. (1996). Abstract.   |
| BL | Penning et al. Synthesis and Biological Evaluation of the 1, 5 -diarylpyrazole class of cyclooxygenase-2 Inhibitors: Identification of 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide (SC-58635, Celecoxib). <u>Journal Of Medicinal Chemistry</u> , 40(9), 1347-65. (1997). |
| BM | Lipsky et al. Outcome of Specific COX-2 Inhibition in Rheumatoid Arthritis. <u>Journal Of Rheumatology</u> , 24 Suppl 49, pp. 9-14. (1997).  |
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FORM PTC-1449 (REV. 7-89)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1079US		SERIAL NO.: 09/154,354 <i>101057,432</i>								
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et al.										
				FILING DATE: September 17, 1998		GROUP: 1627 <i>1639</i>								
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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1079CON7		SERIAL NO.: Not yet known 10/05-7-632	
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et al.		GROUP: Not Yet Known 1639	
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	5 8 5 9 2 5 7	01/12/99	Talley	548	247	08/14/96
	AB	5 8 6 3 9 2 2	01/26/99	Mayer, et al.	514	270	07/02/99
	AC	5 8 4 0 7 3 1	11/24/98	Mayer, et al.	514	289	08/02/95
	AD	5 8 6 9 4 9 8	02/09/99	Mayer, et al.	514	282	07/07/97
	AE	5 8 6 1 4 1 9	01/19/99	Dube, et al.	514	334	07/11/97
	AF	5 7 8 9 4 1 3	08/04/98	Black, et al.	514	255	01/21/97
	AG	5 6 0 4 2 6 0	02/18/97	Guay, et al.	514	605	11/04/93
	AH	5 4 5 8 8 7 9	10/17/95	Singh, et al.	424	400	09/30/94
	AI	5 5 1 6 8 0 3	05/14/96	Raffa	514	570	03/01/95
	AJ	5 8 4 3 4 6 8	12/01/98	Burkoth, et al.	424	448	05/13/96
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AK	Differential Inhibition of Cyclooxygenase-1 (COX-1) and -2 (COX) By NSAIDs: Consequences on Anti-Inflammatory Activity Versus Gastric and Renal Safety, M. Pairet, et al., <i>Inflammopharmacology</i> 4: 61-70, (1996).					
	AL	Differential effects of inhibitors of cyclooxygenase (cyclooxygenase 1 and cyclooxygenase 2) in acute inflammation, Derek W. Gilroy, et al. <i>European J. Pharm</i> 355 pp 211-217, (1998).					
	AM	Cyclooxygenases 1 and 2, J.R. Vane, et al. <i>Annu. Rev. Pharmacol. Toxicol.</i> 38: 97-121, (1998).					
	AN	Analysis of the effects of cyclooxygenase (COX)-1 and COX-2 in spinal nociceptive transmission using indomethacin, a non-selective COX inhibitor, and NS-398, a COX-2 selective inhibitor, Tatsuo Yamamoto, et al. <i>Brain Research</i> 739: 104-110, (1996).					
	AO	Comparative Analgesic Efficacy of Nimesulide and Diclofenac Gels after Topical Application on the Skin, S. Sengupta, et al., <i>Skin Pharmacol. And Applied Skin Phys.</i> 11: 273-278, (1998).					
	AP	Carrageenan-induced hyperalgesia is associated with increased cyclo-oxygenase-2 expression in spinal cord, Cartiona Hay and Jacqueline de Belleruche, <i>Neuro Report</i> 8, 1249-1251, (1997).					
	AQ	The Mechanisms of Action of NSAIDs in Analgesia, Jeremy N. Cashman, <i>Drugs</i> 52 Supp. 5: 13-23, (1996).					
	AR	Differential effects of inhibition of isoforms of cyclooxygenase (COX-1, COX-2) in chronic inflammation, D.W. Gilroy, et al. <i>Inflamm. Res.</i> 47: 79-85, (1998).					
AS	Constitutive Cyclooxygenase (COX-1) and Inducible Cyclooxygenase (COX-2): Rationale for Selective Inhibition and Progress to Date, Don E. Griswold and Jerry L. Adams, <i>Medicinal Research Reviews</i> , Vol. 16, No. 2, pp. 181-206, (1996).						
EXAMINER 				DATE CONSIDERED 6/24/01			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1079CON7		SERIAL NO.: Not Yet Known 101057, 632	
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et al.			
				FILING DATE: Not Yet Known		GROUP: Not Yet Known 1639	
<b>U.S. PATENT DOCUMENTS</b>							
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							YES      NO
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<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
MI	BM	Cyclooxygenase in biology and disease, Raymond N. Dubois, et al., FASEB J. Vol. 12 pp. 1063-1073 (1998).					
	BN	Pharmacology of Meloxicam, A new Non-Steroidal Anti-Inflammatory Drug With An Improved Safety Profile Through Preferential Inhibition of COX-2, G. Engelhardt, British J. Rheumatology, 35 (supp 1):4-12, (1996)					
	BO	Cyclooxygenase 1 Contributes to Inflammatory Responses in Rats and Mice: Implications for Gastrointestinal Toxicity, John L. Wallace, et al. Gastroenterology, 115:101-109 (1998).					
	BP	Distinct isoforms (COX-1 and COX-2) of cyclooxygenase: possible physiological and therapeutic implications, M. Pairet and G. Engelhardt, Fundam. Clin. Pharmacol. 10:1-15, (1996).					
	BO	Involvement of Prostaglandins Produced by Cyclooxygenase-1 in Murine Visceronoception Induced by Phenylquinone, Hidenobu Kusuvara, et al. Prostaglandins 55: 43-49, (1998).					
2	BR	Effect of COX-1 and COX-2 Inhibition on Induction and Maintenance of Carrageenan-Evoked Thermal Hyperalgesia in Rats, D. Dirig, et al. J. Pharmacol. And Experimental Therapeutics Vol. 285, No. 3, pp 1031-1038.					
EXAMINER  M L M				DATE CONSIDERED  6/29/04			
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<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et al.								
				FILING DATE: Not Yet Known		GROUP: Not Yet Known <div style="text-align: center; font-size: 1.2em;">1639</div>						
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*EXAMINER INITIAL	CA	DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
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<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>												
	CK	Effect of meloxicam on postoperative pain after abdominal hysterectomy, J.P. Thompson et al. British Journal of Anaesthesia 84 (2) 151-4 (2000).										
	CL	Intrathecal cyclooxygenase inhibitor administration attenuates morphine antinociceptive tolerance in rats. C.S. Wong et al., British Journal of Anaesthesia 85 (5) 747-51 (2000).										
	CM	Cyclooxygenase inhibitors increase morphine effects on mesolimbic dopamine neurons, M. Melis, et al. Eur. J. Pharmacology 387 (1) R1-R3 (2000).										
	CN	Synergistic antiallodynic effects of spinal morphine with ketorolac and selective COX-1 and COX-2 inhibitors in nerve-injured rats, J.M. Lashbrook, et al. Pain 82 (1) 65-72 (1999).										
	CO	Enhancement of opioid inhibition of gaba-ergic synaptic transmission by cyclo-oxygenase inhibitors in rat periaqueductal grey neurones, Vaughn et al. British Journal of Pharmacology 123 (8) 1479-81 (1998).										
EXAMINER <div style="text-align: center; font-size: 1.5em;">M LA</div>							DATE CONSIDERED <div style="text-align: center; font-size: 1.2em;">6/29/04</div>					
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<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et al.				
				FILING DATE: Not Yet Known		GROUP: Not Yet Known 1239		
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
229	DA	5 4 7 4 9 9 5	12/12/95	Ducharme et al.	514	241	01/10/94	
	DB	5 6 9 1 3 7 4	11/25/97	Black et al.	514	473	05/18/95	
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<b>MC</b>	EA	3 8 0 0 0 4 1	03/26/74	Miller, et al.	424	273	03/02/71	
	EB	4 3 2 2 4 2 7	03/30/82	Buyinski, et al.	424	260	04/16/81	
	EC	4 3 3 8 3 2 4	06/06/82	Gardocki	424	266	03/17/81	
	ED	4 4 0 4 2 1 0	09/13/83	Schmidt	424	260	06/30/82	
	EE	4 4 0 7 8 0 4	10/04/83	Schmidt	424	260	06/30/82	
	EF	4 4 0 7 8 0 5	10/04/83	Schmidt	424	260	06/30/82	
	EG	4 4 6 4 3 7 6	08/07/84	Sunshine, et al.	424	253	10/11/83	
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<b>MC</b>	EJ	2 0 2 3 3 4 9	02/18/91	Canada	A61K	31/44		
	EK	0 2 7 4 8 4 5	07/20/88	EP (A1)	A61K	31/19		
	EL	0 3 8 8 1 2 5	09/19/90	EP (A1)	A61K	31/485		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>								
<b>MC</b>	EM	Pharmacokinetics and Drug Input Characteristics for a Diclofenac-Codeine Phosphate Combination Following Oral and Rectal Administration A. Hansen, et al. <i>Arzneim-Forsch./Drug Res.</i> 46 (II) 57-63 (1996).						
<b>MC</b>	EN	Comparison of a Standard Ibuprofen Treatment Regimen with a New Ibuprofen/Paracetamol/Codeine Combination in Chronic Osteo-arthritis G.K. Vlok, et al. Univ. Stellenbosch and Tygerberg Hospital, Dept. Orthopaedic Surg. pp 3-6, (1987).						
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				FILING DATE: Not Yet Known		GROUP: Not Yet Known <b>1639</b>	
<b>U.S. PATENT DOCUMENTS</b>							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
<b>DL</b>	FA	4 5 6 7 1 8 3	01/28/86	Sunshine, et al.	514	264	12/12/83
	FB	4 5 6 9 9 3 7	02/11/86	Baker, et al.	514	282	02/11/83
	FC	4 5 7 1 4 0 0	02/18/86	Arnold	514	282	12/18/84
	FD	4 5 8 7 2 5 2	05/06/86	Arnold	514	282	12/18/84
	FE	4 6 1 9 9 3 4	12/28/86	Sunshine, et al.	514	277	07/08/85
	FF	4 6 9 0 9 2 7	09/01/87	Voss, et al.	514	282	02/03/86
	FG	4 8 3 9 1 7 6	06/13/89	Pahkhanian, et al.	424	465	12/08/87
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	FK	5 1 9 0 9 4 7	03/02/93	Riess, et al.	514	282	08/16/91
	FL	5 2 4 0 6 9 4	08/31/93	Gwaltney, Jr.	424	45	12/19/91
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EXAMINER <b>BLM</b>				DATE CONSIDERED <b>4/29/04</b>			
<small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>							

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.: 200.1079CON7

SERIAL NO.: Not Yet Known

10/057,632

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE: Not Yet Known

GROUP: Not Yet Known

1639

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
ML	GA	5	4	0	9	9	4	4	04/25/95	Black, et al.	514	359	03/12/93
	GB	5	4	3	6	2	6	5	06/25/95	Black, et al.	514	420	11/12/93
	GC	5	5	1	0	3	6	8	04/23/96	Lau, et al.	514	419	05/22/95
	GD	5	5	2	1	2	1	3	05/28/96	Prasit, et al.	514	443	08/29/94
	GE	5	5	5	0	1	4	2	08/27/96	Ducharme et al.	514	365	05/08/95
	GF	5	5	5	2	4	2	2	09/03/96	Gauthier, et al.	514	368	01/11/95
	GG	5	6	0	4	2	5	3	02/18/97	Lau, et al.	514	415	05/22/95
ML	GH	5	6	3	9	7	8	0	06/17/97	Lau, et al.	514	419	05/22/95

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	GI													
	GJ													
	GK													
	GL													
	GM													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

ML	GN	Anti-inflammatory Drugs and Their Mechanism of Action J.R. Vane, et al. Inflamm. Res. 47, Supplement 2 (1998).
	GO	
	GP	
	GQ	
	GR	

EXAMINER

ML

DATE CONSIDERED

4/6/94

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1079CON7		SERIAL NO.: Not Yet Known <b>161057,632</b>		
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et al.				
				FILING DATE: Not Yet Known		GROUP: Not Yet Known <b>1639</b>		
<b>U.S. PATENT DOCUMENTS</b>								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	HD							
	HE							
	HF							
	HG							
	HH							
	HI							
	HJ							
	HK							
<b>FOREIGN PATENT DOCUMENTS</b>								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	HL							
	HM							
	HN							
	HO							
	HP							
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>								
<i>OK</i>	HQ	Rorarius et al., "Non-Steroidal Anti-Inflammatory Drugs for PostOperative Pain Relief," Curr. Opin. In Anaesthesiology, 7, 358-362). (1994)						
	HR	Hanses et al. "Pharmacokinetics and Drug input Characteristics for a Disclufenac-Codeine Phosphate Combination Following Oral and Rectal Administration," Arzneim.-Forsch./Drug Res., 46(II), Nr. 1,57-63. (1996)						
	HS	Merck Index, Twelfth Edition, Merck & Co. Publishers, page 1194. (1996)						
<i>OK</i>	HT	Goodman and Gillman's: Pharmaceutical Basis of Therapeutics, "Chapter 22: Opioid Analgesics and Antagonists", MacMillan Publishing Co., Inc., pp-494-497, esp. Table 22-1, p. 496. (1980)						
EXAMINER				DATE CONSIDERED				
<i>M L N</i>				<i>6/29/04</i>				
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